DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301)594-4695 Fax:(301)594-4715	6/16/2025-6/19/2025
	FEI NUMBER 3010402691

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. William Jiang, CEO

FIRM NAME	STREET ADDRESS
Foremount Enterprise Co., Ltd.	No. 257, Sec. 5, Changping Rd., Shengang District
CITY, STATE, ZIP CODE, COUNTRY Taichung City, 42944 Taiwan	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

The labels of the medical device(s) do not bear a unique device identifier (UDI) that meet the requirements of 801 Subpart B and 21 CFR 830.

Specifically, your firm has not ensured that your line of private label manufactured Class II Non-Rebreathing Valves, Product Code CBP medical devices your firm has exported and intended for the US market, bear a unique device identifier (UDI).

OBSERVATION 2

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been established.

Specifically, your firm is a Manufacturer of Class II Non-Rebreathing Valves, Product Code CBP and Emergency Manual (Resuscitator) Ventilators, Product Code BTM, medical devices exported and intended for the US market, and your firm's Customer Complaint Handling Procedure, QP824, V.05, dated May 27, 2025, has no requirement to ensure your firm is receiving complaints for your medical

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devices exported and intended for the US market from your US market distributors to ensure your firm reviews and evaluates all complaints in a uniform and timely manner to determine whether an investigation is necessary and are evaluated to determine whether the complaint represents an event, which should be reported to the USFDA under 21 CFR Part 803 - Medical Device Reporting (MDR).

OBSERVATION 3

Written MDR procedures have not been developed and maintained.

Specifically, your firm is a Manufacturer of Class II Non-Rebreathing Valves, Product Code CBP and Emergency Manual (Resuscitator) Ventilators, Product Code BTM, medical devices exported and intended for the US market, and your firm's Medical Device Report (MDR) procedure Product Vigilance and Market Surveillance Procedure, QP752, V.10, dated December 20, 2024, is not adequately established as to date your firm has not established procedure(s) to ensure your firm is receiving complaints for your medical devices exported and intended for the US market from your US market distributors to ensure your firm reviews and evaluates all complaints in a uniform and timely manner to determine whether an investigation is necessary and are evaluated to determine whether the complaint represents an event, that reasonably suggest the failure of a device to meet its performance specifications or otherwise perform as intended, which should be reported to the USFDA under 21 CFR Part 803 - Medical Device Reporting (MDR).

OBSERVATION 4

A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures.

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Specifically, your firm's Validation Management Procedure, QP732, V.05, dated March 26, 2025, and Validation Work Instruction, WI7312, V.02, dated March 27, 2025, have not been adequately established. Your firm is a Manufacturer and Contract Manufacturer of various medical devices to include Class II Non-Rebreathing Valves, Product Code CBP exported and intended for the US market. Your firm conducts Ultrasonic Welding on machines (b)(4) in the manufacturing for your Class II Non-Rebreathing Valves, Product Code CBP exported and intended for the US market; however, you firm was not able to provide protocols and objective evidence to support your related Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) Reports FM-RN-01 and FM-RN-02 dated October 22, 2024.

OBSERVATION 5

Procedures for corrective and preventive action have not been adequately established.

Specifically, your firm's corrective and preventative action (CAPA) procedure Problem Improvement Procedure, QP851, Ver.20, dated December 25, 2024, has not been adequately established. Your firm was not able to provide evidence of an established CAPA system.

OBSERVATION 6

Procedures for acceptance activities have not been adequately established.

Specifically, on June 18, 2025, during the inspection of production and process activities I identified multiple boxes Top Shelf, Par (b)(4) 2, components (approximately (b)(4)), Lot# (b)(4) which per your firm's staff is used in the manufacturing of your Class II Non-Rebreathing Valves, Product Code CBP. However, per your material specifications CPR One-Way Value, Item# (b)(4) for the Class II Non-Rebreathing Valves, Product Code CBP, the correct Top Shelf component is Part# (b)(4) Additionally, your incoming acceptance activities conducted on Lot

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(b)(4) dated May 21, 2025, incorrectly documented Part# (b)(4) which was ultimately accepted by your firm to be used in the manufacturing of Class II Non-Rebreathing Valves, Product Code CBP, for medical devices potentially exported an intended for the US market.

OBSERVATION 7

The acceptance status of product was not identified to indicate conformance or nonconformance with acceptance criteria.

Specifically, on June 18, 2025, during the inspection of production and process activities related to your Class II Non-Rebreathing Valves, Product Code CBP, exported and intended for the US market, I identified multiple raw materials and components used in the manufacturing of medical devices exported and intended for the market, which were not properly identified to ensure that only product which has passed the required acceptance activities are distributed or used.

OBSERVATION 8

Procedures for device history records have not been adequately established.

Your firm's Device History Record (DHR) procedure Product Identification and Traceability Procedure, QP751, V.18, dated July 12, 2024, has not been adequality established. Your firm was not able to provide DHRs for your Class II Non-Rebreathing Valves, Product Code CBP, for medical devices exported and intended for the US market, which demonstrated the devices were manufactured in accordance with the Device Maser Record (DMR).

OBSERVATION 9

Personnel do not have the necessary training and experience to perform their jobs.

Specifically, throughout the inspection key members of your firm who participated and provided

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relevant information were not familiar with the USFDA regulations and requirements for Manufacturers and Contract Manufacturers exporting medical devices intended for the US market to include:

a) 21 CFR Part 803 – Medical Device Reporting

b) 21 CFR Part 807 – Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices

c) 21 CFR Part 820 – Quality System Regulation

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Annotations to Observations

Observation 1:

Observation 2:

Observation 3:

Observation 4:

Observation 5:

Observation 6:

Observation 7:

Observation 8:

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Annotations to Observations

Observation 9:

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."